

**REMARKS/ARGUMENTS**

Claims 1-36 are canceled. Claims 37-65 are newly presented in a preliminary amendment and their entry is respectfully requested.

The specification has been amended to set forth the priority claims of the present application. The specification would also be amended to incorporate subject matter which was incorporated by reference in the parent application.

Satisfaction of 35 U.S.C. §135(b)

35 U.S.C. §135(b) requires that claims for the same or substantially the same subject matter be presented within one year of the issuance of another's patent. *See* MPEP §2307. Applicants would like to call the Examiner's attention to U.S. Patent No. 5,595,753 (enclosed), issued to Hechtman on January 21, 1997. The Hechtman patent was issued with claims drawn to the compositions and uses of L-arginine in treating some of the same anal diseases or conditions as recited in the above-presented claims. While the instant claims were not copied from the '753 patent, the present application and many of the claims of the parent applications concern read on the same subject matter. *See*, for instance, claim 12 of the Hechtman patent.

The present application satisfies the above requirement pursuant to 35 U.S.C. §135(b) as it is a continuation application claiming priority benefit of two applications (U.S. Application No. 08/371,088, filed on January 10, 1995, which is a continuation-in-part of U.S. Application No. 08/250,555, filed on May 27, 1994, now U.S. Patent No. 5,504,117) which were filed before the issuance of the Hechtman patent. The original claims of the U.S. Application No. 08/371,088 are the instantly canceled claims 1-36. Thus, such claims were presented for examination well prior to the issuance of the Hechtman patent. Applicants therefore believe the claims of the present application are not barred by 35 U.S.C. § 135(b).

In addition, if an interference is to be declared, Applicants are entitled to senior party status. The Hechtman patent had an earliest priority date of April 14, 1995, its filing date. The present application is a continuation application claiming priority benefit of two applications (U.S. Application No. 08/371,088, filed on January 10, 1995 and U.S. Application No.

08/250,555, filed on May 27, 1994) with effective filing dates well prior to those of the Hechtman patent.

Applicants would like to call the Examiner's attention to U.S. Patent No. 5,827,889 (enclosed), issued to Cunico on June 27, 1997. The Cunico patent was issued with claims drawn to methods of treating an anal fissure by administering a composition comprising a pharmaceutically acceptable carrier and an acid addition salt of L-arginine. While the instant claims were not copied from the '889 patent, the present application and many of the claims of the parent applications read on the same subject matter. *See*, for instance, claim 1 of the Cunico patent.

The present application satisfies the above requirement pursuant to 35 U.S.C. §135(b) as it is a continuation application claiming priority benefit of two applications (U.S. Application No. 08/371,088, filed on January 10, 1995, which is a continuation-in-part of U.S. Application No. 08/250,555, filed on May 27, 1994, now U.S. Patent No. 5,504,117) which were filed before the issuance of the Cunico patent. The original claims of the U.S. Application No. 08/371,088 are the instantly canceled claims 1-36. Thus, such claims were presented for examination well prior to the issuance of the Cunico patent. Applicants therefore believe the claims of the present application are not barred by 35 U.S.C. § 135(b).

In addition, if an interference is to be declared, Applicants are entitled to senior party status. The Cunico patent had an earliest priority date of April 23, 1996. The present application is a continuation application claiming priority benefit of two applications (U.S. Application No. 08/371,088, filed on January 10, 1995 and U.S. Application No. 08/250,555, filed on May 27, 1994) with effective filing dates well prior to those of the Cunico patent.

AMENDMENTS TO THE SPECIFICATION:

The first sentence of the specification would be amended to recite the priority claim of the present application and therefore adds no new subject matter.

The "Detailed Description" section of the specification of the parent application as originally filed has been further amended to incorporate subject matter indicated in the preceding first sentence of this section to be "incorporated herein by reference." This subject matter

consists of four new paragraphs. The second paragraph is a very close paraphrasal of the complete Abstract (enclosed) of the Rattan, et al. reference (Rattan S., Sarkar A., Chakder S., *Gastroenterology*, (1992 Jul), 103(1):43-50), which is cited at p. 5, line 4, of the specification. The third paragraph is a very close paraphrasal of the complete Abstract (enclosed) of the Chakder, et al. reference (Chakder S., Rattan S., *Am. J. Physiol*, (1993 Jan), 264(1 Pt 1):G7-12), which was cited at p. 5, line 8. The fourth paragraph is a very close paraphrasal of the Abstract (enclosed) of the O'Kelly, et al. reference (O'Kelly T., Brading A., Mortensen N, *Gut*, (1993 May), 34(5):689-93), which was cited in the parent application. Each of these references is also of record in the parent application. Much of the paraphrasal was to make it clear that the instant inventors were not the persons who conducted the research of the studies to be incorporated.

With respect to the written description requirements of 35 U.S.C. §112, each of the above references was specifically pointed out for incorporation by reference in the earliest priority application, U.S. Application No. 08/250,555, filed on May 27, 1994, now U.S. Patent No. 5,504,117. These three references were the only references so pointed out in that document.

According to MPEP §2163.07, "[m]ere rephrasing of a passage does not constitute new matter. Accordingly a rewording of a passage where the same meaning remains intact is permissible." Thus, the present rephrasing of the Abstracts does not constitute new matter.

Pursuant to 37 CFR §6.19, Applicants provide herewith a declaration signed by the inventor stating that the amendatory matter which has been so paraphrased consists of the same matter incorporated by reference in the parent application.

Applicants believe the above amendments to the specification present no new matter and respectfully request their entry.

AMENDMENTS TO THE CLAIMS:

Claims 37-65 are new.

Claim 37 recites:

A method of treating a human patient for an anal disorder selected from one or more of the group consisting of anal fissure, anal ulcer, hemorrhoidal disease, and levator spasm and ameliorating pain associated therewith, comprising administering an effective amount of an organic nitric oxide

donor proximate to, or to, the affected area in the external  
anus and distal anal canal of the patient.

Support for the subject matter of claim 37 is set forth *inter alia* in the first three sentences of the Summary at p. 7 of the specification and also in the first four lines of the Background to the Invention. Support for the subject matter of an "organic nitric oxide donor" is set forth *inter alia* at p. 9, second full paragraph.

Claims 38-48 depend from claim 37:

Support for the recitals of "anal fissure and anal ulcer" of claim 38 is set forth as above.

Support for the recital of "hemorrhoidal disease" of claim 39 is set forth as above.

Support for the recital of "levator spasm" of claim 40 is set forth as above.

Claim 41 recites a nitric oxide donor "capable of releasing nitric oxide under physiological conditions." Support for this subject matter is found *inter alia* in the specification at p. 9, last sentence of the second paragraph.

Claim 42 recites a NO donor "capable of releasing nitric oxide under anal disease treatment conditions." Support for this subject matter is found *inter alia* in the specification at p. 9, last sentence of the second paragraph.

Claim 43 recites "wherein the administering is topical." Support for this subject matter is found *inter alia* in the specification at p. 9, last full paragraph.

Claim 44 recites "wherein the administering is via a suppository." Support for this subject matter is found *inter alia* in the specification at p. 9, last full paragraph.

Claim 45 recites "wherein the organic nitric oxide donor is applied proximate to the affected area in the external anus and distal anal canal of the patient." Support for this subject matter is found in the specification *inter alia* at p. 17, lines 2-5.

Claim 46 recites "wherein the organic nitric oxide donor is applied to the affected area in the external anus and distal anal canal of the patient." Support for this subject matter is found in the specification *inter alia* at p. 16, last paragraph.

Claim 47 depends from claim 37 and recites "wherein the organic nitric oxide donor is formulated in a composition comprising the nitric oxide donor in an amount from 0.01% to 10%

by weight and a physiologically acceptable carrier." Support for this subject matter is found in the specification *inter alia* at p. 11, first full paragraph. Support for the "physiologically acceptable carrier" is found in the specification at p. 9, last full paragraph.

Claim 48 depends from claim 47 and recites "wherein the composition further comprises a carrier selected from the group consisting of white petrolatum, mineral oil, lanolin, distilled water, acetone, and cocoa butter." Support for this subject matter is found in the specification *inter alia* at p. 15, first full paragraph.

Claim 49 depends from claim 47 and recites "wherein the composition further comprises a corticosteroid." Support for this subject matter is found in the specification *inter alia* at p. 9, last paragraph.

Claim 50 depends from claim 47 and recites "wherein the composition further comprises a local anesthetic." Support for this subject matter is found in the specification *inter alia* at p. 9, last paragraph.

Claim 51 depends from claim 47 and recites "wherein the composition is formulated as an ointment, a cream, a gel, or a lotion." Support for this subject matter is found in the specification *inter alia* at p. 13, last full paragraph.

Claim 52 depends from claim 47 and recites "wherein the composition is formulated as a liquid or semisolid." Support for this subject matter is found in the specification *inter alia* at p. 13, last full paragraph.

Claim 53 depends from claim 47 and recites "wherein the composition is formulated as a suppository." Support for this subject matter is found in the specification *inter alia* at p. 9, last full paragraph.

Claim 54 depends from claim 41 and recites "wherein the administering is topical and the nitric oxide donor is formulated as an ointment, a cream, a gel, or a lotion." Support for this subject matter is found in the specification *inter alia* at p. 13, last full paragraph.

Claim 55 depends from claim 41 and recites "wherein the administering is topical and the nitric oxide donor is formulated as a liquid or semisolid." Support for this subject matter is found in the specification *inter alia* at p. 13, last full paragraph.

Claim 56 depends from claim 41 and recites "wherein the nitric oxide donor is

formulated as a suppository." Support for this subject matter is found in the specification *inter alia* at p. 9, last full paragraph.

Claim 57 depends from claim 41 and recites "wherein the organic nitric oxide donor is formulated in a composition comprising the nitric oxide donor in an amount from 0.01% to 10% by weight." Support for this subject matter is found in the specification *inter alia* at p. 11, first full paragraph.

Claim 58 depends from claim 37 and recites "wherein the organic nitric oxide donor is applied to skin or tissue of the anal area." Support for the subject matter of "skin or tissue" is found *inter alia* at p. 14, first line.

Claim 59 depends from claim 47 and recites "wherein the organic nitric oxide donor is applied to skin or tissue of the anal area." Support for the subject matter of "skin or tissue" is found *inter alia* at p. 14, first line.

Claim 60 depends from claim 37 and recites "wherein the organic nitric oxide donor is applied to a hemorrhoid." Support for this subject matter is found *inter alia* in the specification in the paragraph bridging pages 16 and 17, and which discusses contacting the active ingredient with the affected anal area, and the first sentence of the Background at p. 1 which sets forth such conditions as targets for therapy.

Claim 61 depends from claim 37 and recites "wherein the organic nitric oxide donor is applied to an anal fissure or anal ulcer." Support for this subject matter is found *inter alia* in the specification in the paragraph bridging pages 16 and 17, and which discusses contacting the active ingredient with the affected anal area, and the first sentence of the Background at p. 1 which sets forth such conditions as targets for therapy.

New independent claim 62 recites:

A method of treating a human patient having an anal fissure, anal ulcer, hemorrhoid, or spasm of the levator muscle and ameliorating pain associated therewith, comprising applying a composition comprising an effective amount of an organic compound which can release nitric oxide under physiological or anal disease treatment conditions and a physiologically acceptable carrier to an area proximate to, or to, the affected area in the anal canal of the patient.

Appl. No.: Filed herewith  
Amdt. dated: September 22, 2003  
Preliminary Amendment

PATENT

Support for the above subject matter is found as set forth for claims 37, 41, 46 and 48 above.

Claim 63 depends from claim 62 and recites "wherein the affected area has a hemorrhoid." Claim 64 depends from claim 62 and recites "wherein the affected area has an anal ulcer or anal fissure." Support for such subject matter is found in the specification *inter alia* in the first three lines of the "Background of the Invention" and at p. 7, in the first paragraph of the Summary.

Claim 65 depends from claim 62 and recites "wherein the organic compound is formulated as a suppository." Support for this subject matter is found in the specification *inter alia* at p. 17, lines 5-9.

Applicants believe the above amendments introduce no new matter and as such respectfully request their entry.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for examination.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,



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